



May 14, 2001

WARNING LETTER NO. 2001-NOL-22

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Catherine E. Gleason, M.D.
The Breast Center
1121 Mimosa Drive
Oxford, Mississippi 38655

Dear Dr. Gleason:

A representative of the State of Mississippi, acting on behalf of the U. S. Food and Drug Administration (FDA), inspected your facility on May 9, 2001. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal Law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

- Processor quality control records for the month of September 2000 were missing for at least 30% of the operating days for processor 1, [REDACTED] or [REDACTED], room Darkroom at the Site: The Breast Center/Catherine E. Gleason, M.D.

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. This problem has been identified as Level 1, because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 finding that was listed on the inspection report provided to you at the close of the inspection. This Level 2 finding is:

- The facility has not specified adequate written procedures for collecting and resolving consumer complaints or did not follow them when required at the site: The Breast Center/Catherine E. Gleason, M.D.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct the violation noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations; and,
- include sample records that demonstrate proper record keeping procedures, if the findings relate to quality control (Phantom QC, Processor QC)

Please submit your response to:

Patricia K. Schafer, Compliance Branch Director
6600 Plaza Drive, Suite 400
New Orleans, LA 70127
Telephone: (504) 253-4519

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov>.

If you have more specific questions about mammography facility requirements, or about the contents of this letter, please feel free to contact Stacy G. Marshall at (504) 253-4554.

Sincerely,



Carl E. Draper
District Director
New Orleans District Office

cc: Ms. Priscilla F. Butler, M.S.
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